REMARKS

Claims 43 and 45 are currently amended. New claim 63 is added. It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 43-62 under 35 U.S.C. 112, 1st paragraph

Claims 43-62 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. Claim 43 is currently amended. Accordingly, Applicants have fully responded to this rejection. Claim 43, meets the written description requirements. Reconsideration is urged.

The written description requirement of the Patent Code is fulfilled when the patent specification describes the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 USPQ 367 (CCPA 1971).

Under this standard, the Examiner's conclusion that the specification requires more than the example showing the total deletion of the gene, or a substitution of the start codon ATG is plainly incorrect. The specification discloses, and one skilled in the art would clearly recognize, that the scope of the present invention includes isolated mutant host cells in accordance with the claims.

Applicants submit that the specification provides a written description of the claimed invention. The claimed invention is directed to mutant *Bacillus licheniformis* cells which secrete at least 5% less of a secreted polypeptide than the parent host cell when they are cultivated under comparable conditions, wherein the secreted polypeptide has an amino acid sequence which is at least 95% identical to SEQ ID NO: 134. As explained in the specification, the object of the present invention is to reduce or eliminate secreted polypeptide(s) to provide for a cleaner culture. The mutant *Bacillus* host cell, in which the gene encoding the polypeptide represented by SEQ ID NO: 134 is mutated, is not merely an arbitrary selection. Indeed *Bacillus licheniformis* produces an extracellular protein having the amino acid sequence shown in SEQ ID NO: 134 -- a major contaminating protein in various products. The present disclosure provides, *inter alia*, the complete sequence for SEQ ID NO: 134, related DNA SEQ ID NO: 133, and example 1 where the gene encoding a small extracellular protein from *B. licheniformis* is

included in the sequence shown in SEQ ID NO: 133, where the start codon of the protein encoding sequence is the ATG in position 601, and the stop codon is the TAA in position 979. The example shows a vector designed to allow deletion of the entire open reading frame and its construction.

Importantly, the specification continues to describe on page 14, *B. licheniformis* strains, which do not produce the small extracellular protein, and a procedure for their construction.

It is of interest to point out that the specification states the following:

> Accordingly, in a first aspect the invention relates to a *Bacillus licheniformis* mutant host cell derived from a parent *B. licheniformis* host cell, which mutant host cell is mutated in one or more gene(s) encoding one or more secreted polypeptide(s) which is at least 80% identical to one or more of the polypeptides shown in SEQ ID NO's: 2 to 200 . . .still more preferably at least 95% identical, and most preferably at least 97% identical to one or more of the polypeptides shown in SEQ ID NO's: 2 to 200, wherein the mutant host cell secretes at least 5% less of the one or more secreted polypeptide(s) than the parent host cell, when they are cultivated under comparable conditions.

See 1st full paragraph on page 2.

Moreover, the specification explains % identity:

> The degree of identity, or %-identity of polypeptide sequences can suitably be investigated by aligning the sequences using a computer program known in the art, such as "GAP" provided in the GCG program package (Program Manual for the Wisconsin Package, Version 8, August 1994, Genetics Computer Group, 575 Science Drive, Madison, Wisconsin, USA 53711)(Needleman, S.B. and Wunsch, C.D., (1970), Journal of Molecular Biology, 48, 443-453). Using GAP with the following settings for DNA sequence comparison: GAP creation penalty of 5.0 and GAP extension penalty of 0.3".

See page 4.

Further, the specification specifically states:

> A specific example of such a deletion or partial deletion is shown in an example herein, where a gene encoding the native secreted polypeptide shown in SEQ ID NO: 134 is deleted from a *Bacillus licheniformis* host cell. So, a preferred embodiment of the present invention relates to a host cell of the first aspect, which is mutated by a partial or complete deletion of a gene encoding a secreted polypeptide which is at least 80% identical to the polypeptide shown in SEQ ID NO: 134, more preferably at least 85%, still more preferably at least 90%, even more preferably at least 95%, and most preferably at least 97% identical to the polypeptide shown in SEQ ID NO: 134.

See page 5 of the specification.

Examples of mutant host cells falling within the scope of the claimed invention including host cells mutated by a partial or complete deletion of a gene encoding a secreted polypeptide which is at least at least 95%, and at least 97% identicle to the polypeptide shown in SEQ ID NO: 134, are clearly envisioned by an artisan once apprised of Applicants' invention. Accordingly,

an artisan would reasonably conclude that Applicants were not only in possession of the mutant host cells having the complete deletion of the gene encoding the secreted polypeptide, but also that Applicants had possession of highly related mutant host cells, as specified by the claims. Indeed, based on the high level of skill in the art, the phrase "mutant host cell comprises a mutation in a gene encoding a secreted polypeptide which has an amino acid sequence which is at least 95% identical to SEQ ID NO: 134" itself conveys to the artisan that Applicants were in possession of the claimed invention. Applicants have previously explained that it would be apparent to persons skilled in the art that other mutations would result in at least 5% less of the secreted polypeptide. For example, one skilled in the art would appreciate that a substitution of the start codon ATG would result in at least 5% less of the secreted polypeptide.

Notwithstanding the above, the Examiner has not provided sufficient evidence or reasoning to rebut that the specification provides an adequate written description for highly related mutant host cells as claimed. In this regard, the Examiner contends that a number of additional representative species are required to be disclosed. However, given the high degree of identity recited in the claims, an extremely high degree of predictability exists as to the structure and function of the strains falling within the claims.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed mutant host cells to fulfill the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

II. **The Rejection of Claims 43-62 under 35 U.S.C. 112, second paragraph**

Claim 43 is currently amended. Reconsideration is urged.

III: **New claim 63**

New claim 63 is added. The USPTO is authorized to charge the deposition account of Novozymes North America Inc should any additional fees be due, *i.e.* deposit account no. 50-1701.

IV. **Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: November 11, 2008

/Michael W. Krenicky Reg # 45411/

Michael W. Krenicky Reg. No. 45,411
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097